NOV 9 2012

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: Jul 7, 2011

5.3 Revised Date: August 1, 2012

5.4 Submitter:

Address: No.77, keji 1st Road, Guishan Township, Taoyuan County 333, Taiwan, R.O.C.

Phone: +886-03-3287882

Fax: +886-03-3288622

Contact: Clytie Chiou

Establishment Registration Number: 9710603

5.3 Identification of the Device:

Proprietary/Trade name:	VOLTERA Powered Suction Pump, S1001-3 Series
Common Name:	Powered Suction Pump
Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump
Device Classification:	II
Regulation Number:	878.4780
Panel:	General & Plastic Surgery
Product Code:	OMP

5.4 Identification of the Predicate Device:

Predicate Device Name:	NovaSpine Powered Suction Pump PRO-I
Manufacturer:	NovaSpine LLC
510(k) Number or Clearance Information:	K062456
Predicate Device Name:	Prospera PRO-I, PRO-II and PRO-III Negative Pressure Wound Therapy System

Manufacturer: Medica-Rents Co LTD

510(k) Number or Clearance Information: K112458

5.5 Intended Use and Indications for Use of the subject device.

The VOLTERA Powered Suction Pump, S1001-3 Series is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudate, infectious material, and tissue debris which may promote wound healing. The VOLTERA Powered Suction Pump is indicated for removal of exudate from traumatic, dehisced wounds, partial thickness burns, chronic wounds such as pressure ulcers, diabetic foot ulcers, venous leg ulcers, acute wounds, and flaps and grafts.

5.6 Device Description

The VOLTERA Powered Suction Pump, S1001-3 Series is a lightweight, suction device intended for wound management via application of continual or intermittent negative pressure wound therapy to the wound for removal of fluids, including wound exudates, irrigation fluids, and infectious materials. The pump is connected to the wound dressing via a tube connected to a disposable canister. The device provides negative pressure wound therapy to the wound at a range of pressure settings and removes exudates from the wound site to the disposable canister. The device can operate either by a mains power supply or internal battery.

5.7 Non-clinical Testing

A series of in vitro and in vivo preclinical physical and mechanical tests were performed to assess the safety and effectiveness of the VOLTERA Powered Suction Pump. The tests were conducted in accordance with **IEC 60601-1-1 Safety Requirements for Medical Electrical Systems (06/92), Am.1 (11/95), Ed.2 (12/00), IEC 60601-1-2 Electromagnetic Compatibility - Requirements and Tests (04/93), Ed.2 (09/01), Am.1 (09/04), Ed. 2.1 (11/04), ISO 14971:2007 Medical devices- Application of risk management to medical devices**. All the test results demonstrate the performance of VOLTERA Powered Suction Pump meets the requirements of its pre-defined acceptance criteria and intended uses.
The results of the non-clinical testing demonstrate that the VOLTERA Powered Suction Pump is substantially equivalent to the predicate devices.

5.8 Substantial Equivalence Determination

The VOLTERA Powered Suction Pump submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared NovaSpine Powered Suction Pump PRO-I which is the subject of K062456 and Prospera PRO-I, PRO-II and PRO-III Negative Pressure Wound Therapy System which is the subject of K112458. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	**Proposed Device** (VOLTERA Powered Suction Pump, S1001-3 Series)	**Predicate Device** (NovaSpine Powered Suction Pump PRO-I, K062456)	**Predicate Device** (Prospera PRO-I, PRO-II and PRO-III Negative Pressure Wound Therapy System, K112458)
Classification	Class II	Class II	Class II
Code or Federal Regulations	878.4780	878.4780	878.4780
Prescription Medical Devices	YES	YES	YES
Intended Use	The VOLTERA Powered Suction Pump, S1001-3 Series is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess	The NovaSpine Powered Suction Pump PROMI is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing or for the aspiration and removal	The Prospera Negative Pressure Wound Therapy System is indicated for patients that would benefit from a suction device particularly as the device may promote wound healing by removal of wound

	exudate, infectious material, and tissue debris which may promote wound healing. The VOLTERA Powered Suction Pump is indicated for removal of exudate from traumatic, dehisced wounds, partial thickness burns, chronic wounds such as pressure ulcers, diabetic foot ulcers, venous leg ulcers, acute wounds, and flaps and grafts.	of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from a patient's airway or respiratory support system either during surgery or at the patient's bedside.	exudate, debris, and infectious material or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from the patient's airway or respiratory support system. The Prospera Negative Pressure Wound Therapy may be used during surgery or at the patient's bedside and is indicated for home use.
Model	S1001-3 Series	PRO-I	PRO-I, PRO-II, PRO-III
Indications for Use	The Voltera suction pump is indicated on use with patients with the following wounds: ➢ Traumatic ➢ Dehisced wounds ➢ Partial thickness burns (the epidermis and some portion of the dermis have been burned or	For management of chronic, acute, traumatic, sub acute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	For management of chronic, acute, traumatic, sub acute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

	injured) ➢ Chronic wounds (pressure ulcers,diabetic foot ulcers, venous leg ulcers) ➢ Acute wounds ➢ Traumatic ➢ Flaps and grafts		
Contraindications	Contraindicated for patients with the following conditions: 1. Presence of necrotic tissue 2. Malignancy 3. Untreated Osteomyelitis 4. Untreated malnutrition 5. Exposed arteries, veins, nerves, or organs 6. Use over anastomotic sites	The PRO-I is contraindicated in the presence of: 1. Necrotic tissue 2. Unexplored or non-enteric fistulas 3. Untreated osteomyelitis 4. Malignancy in the wound 5. Exposed arteries, veins, or organs	The PRO-I, PRO-II, PRO-III is contraindicated in the presence of: 1. Necrotic tissue 2. Unexplored or non-enteric fistulas 3. Untreated osteomyelitis 4. Malignancy in the wound 5. Exposed arteries, veins, or organs
Specification	Suction: 2.5 liters/min	Suction: 9 liters/min	Suction: 9 liters/min
	Maximum Vacuum: -200 mmHg	Maximum Vacuum: -200 mmHg	Maximum Vacuum: -200 mmHg
	Noise: 30dba at 190 cm	Noise: 35 dba	Noise: 35 dba
	Weight: 1.35 kg	Weight: 2.8 kg	Weight: 1.8~2.8 kg
	Voltage: 100-240V /	Voltage: 100-240V /	Voltage: 100-240V /

	50-60Hz	50-60Hz	50-60Hz
	Operation: Continuous and Intermittent	Operation: Continuous and Intermittent	Operation: Continuous and Intermittent
	Battery Operation: 24~48hrs depending on use	Battery Operation: 24~48hrs depending on use	Battery Operation: 24~48hrs depending on use
	Dimensions: 170*160*90 mm	Dimensions: 290*359*130 mm	Dimensions: 290*359*130 mm
Consumable/ Disposable components	Collection canister (secretion container)	Collection canister (secretion container)	Collection canister (secretion container)
	Related hoses (tubing)	Related hoses (tubing)	Related hoses (tubing)
	Hose connectors	Hose connectors	Hose connectors
	Filters	Filters	Filters
	Other accessories	Other accessories	Other accessories

5.9 Conclusion

After analyzing bench tests, electrical safety testing data, it can be concluded that VOLTERA Powered Suction Pump, S1001-3 Series is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Suzric Enterprise Co., Ltd.
% AcmeBiotechs Co., Ltd.
Mr. Michael Lee
No. 77, Keji 1st Road
Guishan Township
Taoyuan County, 333 Taiwan

Letter Dated: November 9, 2012

Re: K112853
Trade/Device Name: Voltera Powered Suction Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 02, 2012
Received: October 04, 2012

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K112853

Device Name: VOLTERA Powered Suction Pump, S1001-3 Series

Indications for Use:

The VOLTERA Powered Suction Pump, S1001-3 Series is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudate, infectious material, and tissue debris which may promote wound healing. The VOLTERA Powered Suction Pump is indicated for removal of exudate from traumatic, dehisced wounds, partial thickness burns, chronic wounds such as pressure ulcers, diabetic foot ulcers, venous leg ulcers, acute wounds, and flaps and grafts.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112853